

## **WHAT IS CLAIMED IS:**

- 1                   1.       A topical delivery composition in a pressurized container, said  
2 composition comprising:  
3                   up to 15% w/w of at least one pharmaceutically active compound, or its  
4 pharmaceutically acceptable salt or a prodrug thereof;  
5                   from about 83% to about 97.9% w/w of a quick-breaking foaming agent; and  
6                   from about 2% to about 7% w/w of an aerosol propellant selected from the  
7 group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons  
8 and a mixture thereof,  
9 wherein said composition is a quick-breaking temperature sensitive foam after release from  
10 said container.
- 1                   2.       The composition of claim 1, wherein said at least one pharmaceutically  
2 active compound is an antibiotic agent.
- 1                   3.       The composition of claim 2, wherein said at least one antibiotic agent  
2 is clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.
- 1                   4.       The composition of claim 3, wherein said at least one pharmaceutically  
2 active compound is clindamycin phosphate.
- 1                   5.       The composition of claim 1, wherein said at least one pharmaceutically  
2 active compound comprises a combination of active agents.
- 1                   6.       The composition of claim 5, wherein said combination of active agents  
2 comprises at least two agents selected from the group consisting of an antibiotic agent, an  
3 antifungal agent, a retinoid, a retinoid derivative, salicylic acid, azelaic acid, sodium  
4 sulfacetamide, and benzoyl peroxide.
- 1                   7.       The composition of claim 5, wherein said combination of active agents  
2 comprises clindamycin phosphate and tretinoin.
- 1                   8.       The composition of claim 5, wherein said combination of active agents  
2 comprises clindamycin phosphate and benzoyl peroxide.

- 1                   **9.**       The composition of claim **1**, wherein said quick-breaking foaming  
2 agent comprises a C<sub>1</sub>-C<sub>6</sub> alcohol and water.
- 1                   **10.**     The composition of claim **9**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is from about 1:7 to about 1:16.
- 1                   **11.**     The composition of claim **10**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is about 1:7.
- 1                   **12.**     The composition of claim **10**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is about 1:16.
- 1                   **13.**     The composition of claim **1**, wherein said quick-breaking foaming  
2 agent comprises a C<sub>1</sub>-C<sub>6</sub> alcohol, a C<sub>14</sub>-C<sub>22</sub> alcohol, water, and a surfactant.
- 1                   **14.**     The composition of claim **13**, wherein the foam breaking temperature  
2 of said quick-breaking temperature sensitive foam is from about 30°C to about 36°C.
- 1                   **15.**     The composition of claim **13**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is about 1.7:1.
- 1                   **16.**     The composition of claim **13**, wherein said surfactant is present in an  
2 amount of from about 0.1% to about 10 % w/w.
- 1                   **17.**     The composition of claim **16**, wherein said surfactant is selected from  
2 the group consisting of an ethoxylated non-ionic surfactant, an ethoxylated ionic surfactant,  
3 and a mixture thereof.
- 1                   **18.**     The composition of claim **16**, wherein said surfactant is a polysorbate.
- 1                   **19.**     The composition of claim **13**, further comprising an emollient.
- 1                   **20.**     The composition of claim **19**, wherein said emollient is a polyol.
- 1                   **21.**     The composition of claim **20**, wherein said polyol is selected from the  
2 group consisting of propylene glycol, glycerol, and a mixture thereof.

- 1                   **22.**     The composition of claim **13**, wherein the amount of said C<sub>1</sub>-C<sub>6</sub>  
2 alcohol in said quick-breaking foaming agent is from about 55% to about 65% w/w.
- 1                   **23.**     The composition of claim **22**, wherein said C<sub>1</sub>-C<sub>6</sub> alcohol is selected  
2 from the group consisting of methanol, ethanol, propanol, butanol, and a mixture thereof.
- 1                   **24.**     The composition of claim **23**, wherein said C<sub>1</sub>-C<sub>6</sub> alcohol is ethanol.
- 1                   **25.**     The composition of claim **23**, wherein said C<sub>1</sub>-C<sub>6</sub> alcohol is a mixture  
2 of ethanol and at least one other C<sub>1</sub>-C<sub>6</sub> alcohol.
- 1                   **26.**     The composition of claim **13**, wherein the amount of said C<sub>14</sub>-C<sub>22</sub>  
2 alcohol in said quick-breaking foaming agent is from about 1% to about 5% w/w.
- 1                   **27.**     The composition of claim **26**, wherein said C<sub>14</sub>-C<sub>22</sub> alcohol is a C<sub>14</sub>-C<sub>20</sub>  
2 alcohol.
- 1                   **28.**     The composition of claim **27**, wherein said C<sub>14</sub>-C<sub>20</sub> alcohol is selected  
2 from the group consisting of cetyl alcohol, stearyl alcohol, and a mixture thereof.
- 1                   **29.**     The composition of claim **28**, wherein said C<sub>14</sub>-C<sub>20</sub> alcohol is a mixture  
2 of cetyl alcohol and stearyl alcohol.
- 1                   **30.**     The composition of claim **29**, wherein the ratio of cetyl alcohol to  
2 stearyl alcohol is from about 60:40 to about 80:20.
- 1                   **31.**     The composition of claim **30**, wherein the ratio of cetyl alcohol to  
2 stearyl alcohol is about 70:30.
- 1                   **32.**     The composition of claim **1**, wherein said composition comprises water  
2 in an amount up to 90% w/w.
- 1                   **33.**     The composition of claim **13**, wherein said composition comprises  
2 water in an amount from about 30% to about 40% w/w.
- 1                   **34.**     The composition of claim **13**, further comprising a pH adjusting agent.

1                   **35.**     The composition of claim **34**, wherein the pH of said composition is  
2     from about pH 4.0 to about pH 9.0.

1                   **36.**     The composition of claim **35**, wherein the pH of said composition is  
2     from about pH 4.0 to about pH 6.5.

1                   **37.**     The composition of claim **1**, wherein said composition comprises:  
2                   from about 0.1% to about 10% w/w of at least one pharmaceutically active  
3     compound, or its pharmaceutically acceptable salt or a prodrug thereof;  
4                   from about 83% to about 97.9% w/w of a quick-breaking alcoholic foaming  
5     agent; and  
6                   from about 2% to about 7% w/w of an aerosol propellant selected from the  
7     group consisting of a hydrocarbon, a chlorofluorocarbon, and a mixture thereof.

1                   **38.**     The composition of claim **1**, wherein said composition does not  
2     contain a C<sub>1</sub>-C<sub>6</sub> alcohol.

1                   **39.**     A method for the percutaneous treatment of acne, said method  
2     comprising:  
3                   applying a quick-breaking temperature sensitive foam composition to the skin  
4     of a subject in need thereof, said composition comprising an effective amount of at least one  
5     pharmaceutically active compound, wherein said at least one pharmaceutically active  
6     compound is at least clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.

1                   **40.**     The method of claim **39**, wherein said at least one pharmaceutically  
2     active compound is clindamycin phosphate.

1                   **41.**     The method of claim **39**, wherein said at least one pharmaceutically  
2     active compound is a combination of clindamycin phosphate and tretinoin.

1                   **42.**     The method of claim **39**, wherein said at least one pharmaceutically  
2     active compound is a combination of clindamycin phosphate and benzoyl peroxide.

1                   **43.**     The method of claim **39**, wherein the foam breaking temperature of  
2     said quick-breaking temperature sensitive foam composition is from about 30°C to about  
3     36°C.

1                   **44.**     The method of claim **39**, wherein the quick-breaking temperature  
2 sensitive foam composition is dispensed from a pressurized container comprising:  
3                   up to 15% w/w of at least clindamycin, or a pharmaceutically acceptable salt  
4 or a prodrug thereof;  
5                   from about 83% to about 97.9% w/w of a quick-breaking foaming agent; and  
6                   from about 2% to about 7% w/w of an aerosol propellant selected from the  
7 group consisting of a hydrocarbon, a chlorofluorocarbon, and a mixture thereof.

1                   **45.**     The method of claim **44**, further comprising from about 0.01% to about  
2 0.5% w/w of tretinoin.

1                   **46.**     The method of claim **44**, further comprising from about 0.5% to about  
2 10% w/w of benzoyl peroxide.

1                   **47.**     The method of claim **44**, wherein said quick-breaking foaming agent  
2 comprises a C<sub>1</sub>-C<sub>6</sub> alcohol and water.

1                   **48.**     The method of claim **47**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is from about 1:7 to about 1:16.

1                   **49.**     The method of claim **48**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is about 1:7.

1                   **50.**     The method of claim **48**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is about 1:16.

1                   **51.**     The method of claim **44**, wherein said quick-breaking foaming agent  
2 comprises a C<sub>1</sub>-C<sub>6</sub> alcohol, a C<sub>14</sub>-C<sub>22</sub> alcohol, water, and a surfactant.

1                   **52.**     The method of claim **51**, wherein the ratio of said C<sub>1</sub>-C<sub>6</sub> alcohol to  
2 water is about 1.7:1.

1                   **53.**     A method for modulating a foam characteristic of a quick-breaking  
2 temperature sensitive foam composition comprising a quick-breaking foaming agent, said  
3 method comprising:  
4                   changing the C<sub>1</sub>-C<sub>6</sub> alcohol to water ratio in said quick-breaking alcoholic  
5 foaming agent.

1                   **54.**     The method of claim **53**, wherein the modulated foam characteristic is  
2 selected from the group consisting of clarity, density, viscosity, foam bubble size, foam  
3 expansion rate, foam flow rate, foam breaking temperature, and combinations thereof.

1                   **55.**     The method of claim **54**, wherein the modulated foam characteristic is  
2 the foam breaking temperature.

1                   **56.**     A method for increasing the shelf-life of clindamycin phosphate, said  
2 method comprising:  
3                   dissolving said clindamycin phosphate in a pressurized container comprising a  
4 mixture of a C<sub>1</sub>-C<sub>6</sub> alcohol, a C<sub>14</sub>-C<sub>22</sub> alcohol, water, a surfactant, and a hydrocarbon  
5 propellant.

1                   **57.**     The method of claim **56**, wherein said mixture further comprises a pH  
2 adjusting agent.

1                   **58.**     The method of claim **57**, wherein the pH of said mixture is from about  
2 pH 4.0 to about pH 6.5.

1                   **59.**     The method of claim **58**, wherein the pH adjusting agent is a base.

1                   **60.**     The method of claim **58**, wherein the pH adjusting agent is an acid, an  
2 acid salt, or mixtures thereof.

1                   **61.**     The method of claim **56**, wherein the inner surface of the container is  
2 lined with a chemically inert lining.

1                   **62.**     The method of claim **61**, wherein said chemically inert lining is a  
2 polyamide-imide.

1                   **63.**     A use of a pharmaceutical composition in a pressurized container in  
2 the preparation of a medicament for the percutaneous treatment of acne, said composition  
3 comprising:

4                   up to 15% w/w of at least one pharmaceutically active compound, or its  
5 pharmaceutically acceptable salt or a prodrug thereof;

6                   from about 83% to about 97.9% w/w of a quick-breaking foaming agent; and

7                    from about 2% to about 7% w/w of an aerosol propellant selected from the  
8 group consisting of a hydrocarbon, a chlorofluorocarbon, and a mixture thereof,  
9                    wherein said composition is a quick-breaking temperature sensitive foam after  
10 release from said container.